REMARKS

As a preliminary matter, Applicants wish to thank the Examiner for the telephonic interviews on December 22, 2003, and January 5, 2004, in this case. The present amendments and remarks are made in view of the interviews, the final Office Action mailed September 15, 2003, and the Advisory Action mailed February 10, 2004.

Support for Amendments

In view of the present amendment to claim 1, claims 36-38 are reintroduced. Support for the amendment to claim 1 is found in claims 35-39 and the specification at page 19, lines 10-14. No new matter is introduced by this amendment.

The Examiner refused to enter the present amendment to claim 1, asserting that

> [t]he presently filed proposed amendments do not have support in the specification as filed. Page 19 lines 10-14 do not exclude IgE as an antibody in the possible compositions. *Advisory Action*, Note to paragraph 2(b); emphasis added.

Applicants respectfully disagree with this basis of refusal and submit that there is neither a requirement that the present claim amendment encompass the full scope of the disclosure, nor is there a requirement that the application specifically direct the exclusion of IgE. Applicant is permitted, for any reason, to claim less than what is disclosed. See, M.P.E.P. § 2173.05(i).

The facts of the instant case are virtually identical to those in *In re Johnson*, 558 F.2d 1008 (C.C.P.A. 1977). The *Johnson* applicant disclosed 50 examples of a chemical constituent, E, and 23 examples of another constituent, E', that could be used in the general chemical formula: -(O-E-O-E')-. For reasons of unpatentability, the claims were amended to encompass fewer than all of the exemplified possibilities. These claims were

finally rejected by the Patent Office for lacking substantive support because the specification did not specifically exclude the unpatentable possibilities. The question before the Johnson court was "whether, after exclusion from the original claims of two species specifically disclosed in the [application], the [] disclosure satisfies §112, first paragraph, for the 'limited genus' now claimed." *Id.* at 1017-1018.

The *Johnson* court, in reversing the Patent Office rejection, reasoned that

> [i]nventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. *Id.* at 1018, quoting *In re Wertheim*, 541 F.2d 247, 263 (C.C.P.A. 1976).

And that "[i]t is for the inventor to decide what bounds of protection he will seek." *Id.* at 1018, citing *In re Saunders*, 444 F.2d 599, 607 (C.C.P.A. 1971). The *Johnson* court cautioned that

> [t]he notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. *In re Johnson* at 1019.

The *Johnson* court held, therefore, that applicants "are merely excising the invention of another, to which they are not entitled, and are not creating an 'artificial subgenus' or claiming 'new matter'." *Id.* at 1019; emphasis added.

As in *Johnson*, Applicants disclose a genus exemplified by several specific members, one of which Applicants are attempting to exclude from the scope of the claims. In the instant case, Applicants teach recombinant polyclonal antibodies that react with an allergen. The specification discloses that suitable antibody isotypes include IgG, IgM, IgA, IgD, and IgE. In view of the prior art, Applicants have specifically amended the claims to exclude compositions containing recombinant IgE. The resulting claim is

limited to immunoglobulin isotypes that are specifically exemplified in the application. Thus, Applicants are not creating an "artificial subgenus" where none existed. Accordingly, the present claim amendments should be entered and the new matter and inadequate written description rejections should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

All pending claims stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,470,371 ("the '371 patent") in view of U.S. Patent No. 5,789,208 ("the '208 patent"). The Examiner relies on the process disclosed in the '371 patent that creates a polyclonal antibody composition that is free from allergen as a precursor to the final pharmaceutical composition that contains the allergen. The Examiner asserts that it would have been obvious to a skilled artisan to create the allergen-free polyclonal antibody mixture using the recombinant techniques of the '208 patent.

In order to establish a *prima facie* case of obviousness, the prior art must teach or suggest every limitation of the claim. M.P.E.P. § 2143.03. The claims have been amended to encompass only allergen-free recombinant polyclonal antibody compositions that are free from IgE and may contain one or more of an IgG, IgM, IgA, and IgD. In contrast to the IgE-free compositions of the instant invention, the polyclonal antibody compositions of the '371 patent are purified from blood plasma samples which necessarily contain IgE. The '371 patent does not teach or suggest separating any of the immunoglobulin types and characterizes the resulting compositions as containing 0.5% IgE (col. 8, line 31). Furthermore, nothing in the '371 patent even suggests the desirability or technical feasibility of eliminating the IgE. In fact, because the methods and compositions of the '371 patent are used to desensitize patients to the allergen of interest, the elimination of IgE maybe unnecessary and its presence might be desirable.

The '208 patent does not provide what the '371 patent lacks. Nothing in the '208 patent suggests making a polyclonal antibody composition free from IgE that is capable

of reacting with or binding to proteins or epitopes derived from an inhaled, ingested, or airborne allergens. The '208 patent is concerned with the treatment of neoplastic diseases, infectious diseases, and genetic disorders using recombinant polyclonal antibodies that bind to disease-specific antigens. A combination of the '371 patent and the '208 patent, as the Examiner suggests, would result in a recombinant polyclonal antibody mixture that mimics the antibody composition purified from blood plasma—one necessarily containing IgE. Thus, Applicants submit that the combination of prior art asserted by the Examiner does not teach or suggest every limitation of the presently amended claims. Accordingly, this rejection should be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is requested. Enclosed is a petition to extend the period for replying for three months, to and including March 15, 2004. Applicants point out that a one month extension, to and including January 15, 2004, has been previously filed in this case. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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